**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF MICHIGAN**

ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI, as parent-guardians and next friend to their minor children, D.W.L., R.F.K., and C.K.K.;

SHANNON LAPORTE, as parent-guardian and next friend to her minor children, M.T.L. and E.M.O.;

and

LYNNETTE WIEGAND, as parent-guardian and next friend to her minor children, L.R.W., C.J.W., H.J.W., and M.L.W.

*Plaintiffs*

v.

ELIZABETH HERTEL,
sued in her official capacity;

DR. SANDIP SHAH,
sued in his official capacity;

DR. SARAH LYON-CALLO,
sued in her official capacity;

MARY KLEYN,
sued in her official capacity; and

DR. ANTONIO YANCEY,
sued in his official capacity

*Defendants*

Case No.: 18-cv-10472

Hon. Thomas L. Ludington,
District Court Judge

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**RESPONSE IN OPPOSITION TO THE STATE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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## COUNTER STATEMENT OF QUESTION(S) PRESENTED

Should summary judgment be granted to the State Defendants?

Answer: No

**MOST RELEVANT AUTHORITY**

FRCP 56

*Kanuszewski v. MDHHS*, 927 F.3d 396 (6th Cir. 2019)

## INTRODUCTION

The State Defendants' summary judgment motion is heavy with platitudes and yet far too light in meeting their constitutional burdens. Despite attempts to wrap the hopeful success of their motion on how noble newborn screening is, this case is solely about what happens ***after*** that screening is done. *Kanuszewski v. Mich. Dep't of Health & Hum. Servs.*, 927 F.3d 396, 406 (6th Cir. 2019). Their basic argument is that "enough" unknowing consent was obtained to allow the State to do whatever it wants, post-screening, with the newborn blood spots as well as the highly personal data they extracted without any parental consent. On this record, that is simply untrue and unsupported. For two of the nine infants is case, there was and is no consent at all. For the remaining seven, each parent confirmed that the actions of the State Defendants were done "without our sufficient informed consent." These Defendants have not shown otherwise.

Even more problematic is their framing of the motion; the Sixth Circuit has already established the law of the case which must be followed. The higher court explained what constitutes a violation of the substantive due process and what constitutes a Fourth Amendment violation. Plaintiffs proved the constitutional violations based on those standards. By *Kanuszewski*, the burden shifted to the Defendants; they then failed to meet

it. They instead simply gift-wrapped their argument in public policy platitudes. Again, this is not good enough for this type of constitutional challenge. Because the State Defendants failed their burden, summary judgment cannot be granted in their favor.

## COUNTER STATEMENT OF FACTS

Plaintiffs incorporate by reference the facts, arguments, and supporting evidence in their Motion for Summary Judgment. **ECF No. 135.** A brief summary follows.

When a new life comes into this world as an infant at a Michigan hospital, the State Defendants' prior-made plans, made without discussion or permission of the parents, swiftly move into action. Using a state statute, the State Defendants command the birthing medical professional to use a skin-piercing device to prick the heel of the newborn and extract an excessive amount[1] of blood, in the form of "spot" samples, for a series of newborn medical "screenings." See MCL 333.5431. These screenings are not done at the birthing hospital or in a parent-selected medical center, but instead at a government-mandated and operated blood and specimen

[1] To complete all screening, the State Defendants need less than a single spot. However, they force the birthing professional to take at least five but usually six spots. See **ECF No. 147, PadeID.4198; ECF No. 147-2, PageID.4244; Exhibit G** (bates-stamp p001322). So while the total volume of blood is not physically a lot, when compared to the amount needed for screening, it is five (5) times more than needed.

testing laboratory. MCL 333.5431(2). A single spot (of the five or six seized) is used to tested against more than fifty diseases (none of which are transferrable or communicable) which is completed within one or two days of specimen delivery to the government laboratory. **Exhibit A**.[2] More than 99.25% of all the screenings come out negative[3] (which is great, of course!). For those extremely rare number of infants that have a possible positive, the State notifies the infants' medical professional for further formal testing and to merely suggest follow-up treatment if that later private medical diagnostic testing confirms a diagnosis.[4] ***Id.*** If the screening is negative, the parents never hear from the State Defendants (or the Biobank) ever again, despite using or marketing their infants' blood and their deeply-private medical and genetic information/data. **ECF No. 135-41, PageID.2420.**

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[2] https://www.michigan.gov/documents/mdch/MI_NBS_Guide_368636_7.pdf

[3] The State Defendants' numbers are a bit bleary. Since 1965, Michigan has, on average, about 120,000 annual live births (though declining). See https://www.mdch.state.mi.us/osr/natality/tab1.1.asp. The State Defendants assert that ≈7,200 infants have been flagged with a potential positive result since 1965. **ECF No. 147, PageID.4199.** That means of the nearly seven million births since 1965, about 1/10$^{th}$ of 1% (000.1%) of infants have been flagged by a positive screen. Of that, the State Defendants do not disclose how many would been diagnosed anyways by routine testing undertaken at the hospital for normal live birthing medical screenings. The scope of the State's intrusion in invading everyone's privacy is immense while the harm sought to be alleviated is for an extreme narrow minority of infants. Yet, even if an infant is detected with the disease, the State offers no assistance to combat that later confirmed diagnosis. See Footnote 4.

[4] Some have questioned this testing-but-no-treatment concept as unconstitutional. Anne Hart, *An Insufficient Screening: The Constitutionality of Michigan's Newborn Screening Program*, 61 B.C. L. Rev. E.Supp. II.-213 (2020), *available at* https://lawdigitalcommons.bc.edu/bclr/vol61/iss9/18.

As structured by the Sixth Circuit on remand, none of the above is being or can yet be challenged. However, once testing is done, the State Defendants undertake two distinct and unlawful set of actions which are challenged in this case. First, the State Defendant seize and keep, in the government's files and databases, the infants' personal and deeply-private medical and genetic information/data extracted during the screenings. [5] **S**ee also **ECF No. 135-42, PageID.2439**. No informed parental consent was ever obtained to authorize that. **Supp. Dec. ¶6, ECF No. 151-6, PageID.5146-5147.** As for the remaining blood spots themselves—which were never needed in the first place—the "residual" blood spots are again seized and retained by the State Defendants—one spot into the BioTrust for Health's Terminal Road warehouse in Lansing and the others transferred to a non-profit corporation called the Michigan Neonatal Biobank in Detroit's Tech Town.[6] **Exhibit H**[7]; see also **ECF No. 147-2, PageID.4244.** To have even come into possession these blood spots in the first place, no consent or permission was ever sought or secured for the blood draw via the heel

[5] The State has produced this trove of medical data to the undersigned counsel but it is not being attached to this filing for privacy reasons.

[6] The Biobank has a separate board of directors. **Exhibit B.**

[7] The documents are litigation summaries created and supplied by the State Defendants confirming the physical chain of events for the blood spots of each infant. The last two boxes in the right-hand column confirm the current retention of the spots at the BioTrust's Terminal Road warehouse and the Biobank's warehouse at Tech Town.

pricking by the State Defendants or their conscripted agents from the infants' parents. MCL 333.5431(2).[8]

So, what should the State Defendants have done? They should have simply returned or destroy them as the actual purpose of their seizure—to test for the fifty-plus diseases—is fully complete. Instead, the State Defendants want to make the extra blood spots (they unnecessarily extracted) available for non-DHHS researchers' use for a fee. While clothed in broad righteousness of public health, this retain-to-sell model of biobanking was created to be operated as a money-making enterprise. **ECF No. 135-7**. But buyers are not immediately available. So, the State Defendants came up with a plan in 2010 to store the blood spots—indefinitely[9]—and later sell them when buyers (usually for-profit research companies or university researchers) express interest. **ECF No. 135-16, PageID.2200**; see also **Exhibit D.** Blood samples are regularly sold for

[8] Interesting, Michigan law requires that certain medical tests be performed by "health professional in charge of the care of a newborn infant." MCL 333.5431(1). However, the statute then provides that "[t]he department may require that the tests be performed by the department." MCL 333.5431(2). Query: why can't parents simply have the tests done themselves so as to avoid the blood spot dragnet? See https://www.perkinelmergenomics.com/how-to-order/index.html.

[9] There is a disconnect in how long these samples are kept. According to policy, they are kept indefinitely. **ECF No. 135-22, PageID.2226** while in other documentation it is 100 years, **ECF No. 147-4, PageID.4249**; see also **ECF No. 84, PageID.1316.** There is no explanation why the different retention periods in different publications.

money payment.[10] E.g., **Exhibit C;** see also **Exhibit G** (bates-stamp p001327-p001328). The goal was to make millions of dollars. **ECF No. 135-7, PageID.2107** (Biobank's business plan sought to create "a significant revenue stream of several million dollars").

Plaintiffs are four parents of nine minor children who have been involuntarily subject to the Michigan Newborn Screening Program, the State's intra-department program known as the Michigan BioTrust for Health, and have had their blood spots and related data retained, stored, and made available for use (at any time and without notice) with/by the Michigan Neonatal Biobank. **Exhibit H.** The nine infants in his case can be drawn into two groups—the pre-2010 births and the post-2010 births.

For two of the infants, D.W.L. and M.T.L., the State Defendants never asked for or received consent from their parents to retain, store, sell, or otherwise use the extracted samples of D.W.L. and M.T.L. due to having been born before May 2010. See **ECF No. 135-25, PageID.2236-2237** (¶11); **ECF No. 135-26, PageID.2252** (¶11). The State Defendants offer no legal authority proving the MDHHS IRB can provide consent in place of a parent.

[10] The State Defendants assert that the blood spots of these nine infants have not been used to date. However, they have not disavowed they will never be used for some purpose for which consent was not first obtained.

For the other seven infants born after 2010, the State Defendants have presented "consent cards" which they assert grant unlimited permission to conduct "health research" or "medical research" by third parties and those to whom they sell the blood spots. Yet, each consent card was executed without first obtaining informed parental consent. Each plaintiff-parent in this case avers that no one communicated in "sufficient enough detail" as to "the risks, the benefits and any alternatives regarding the retention, storage, or uses of the blood samples by third parties like the Michigan Neonatal Biobank or third-party researchers and scientists over whom [the parents] have no control." **ECF No. 135-25, ¶16; ECF No. 135-26, ¶16; ECF No. 135-27, ¶14.** They also confirm that none authorized the State Defendants to transfer their children's blood spots to the Michigan Neonatal Biobank, Inc (or its Director, Dr. Antonio Yancey). **ECF No. 135-25, ¶¶17-19; ECF No. 135-26, ¶¶17-19; ECF No. 135-27, ¶¶15-17.** Before this lawsuit started and before the aid of counsel, no parent knew, realized, or understood that the Defendants (including its partners like the Biobank and Dr. Yancey) indefinitely retained, marketed, and made the children's blood spots available for distribution, use, testing, and other uses, including by for-profit and academic researchers and scientists, who extract and use children's personal and deeply-private medical and genetic information/data for their

own research projects—whether for-profit or otherwise. **ECF No. 135-25, ¶8; ECF No. 135-26, ¶8; ECF No. 135-27, ¶8.** It was not because these parents were somehow ignorant or complacent at the time of their children's birth—it was all part of the common scheme concocted by Defendants to keep parents uninformed or under-informed. See Elizabeth R. Eisenhauer, Ph.D., RN, *Mothers' Decisions About Donating Newborns' Blood Spots for Research: A Qualitative Study*, 33 J. PERINAT. NEONAT. NURS. 361 (2019) (**ECF No. 135-28**). From the parents' perspective, they never authorized the retention, marketing, use, sale, transfer, or even gifting of their children's blood spots by the Biobank, its director, or the State Defendants for third party use, yet that is what is happening today. **Exhibit I**. In fact, the parents never authorized the Biobank (or its Director, Dr. Antonio Yancey) to take possession, control, or custody of the children's blood (which contains deeply private medical and genetic information of our children) from the State Defendants. And had they "known the full and complete scope of the Newborn Screening Program, the Michigan BioTrust for Health, and Michigan Neonatal Biobank, [they] would have never provided any consent or authorization for any part of this program as it is both invasion and evisceration of [the] children's personal and medical privacy and personal autonomy, and improperly invades [the] rights as parents to make all

decisions concerning the medical care of [the] children." **ECF No. 135-25, ¶21; ECF No. 135-26, ¶21; ECF No. 135-27, ¶23.** No parent even remembers signing these documents. **ECF No. 135-25, ¶13; ECF No. 135-26, ¶13; ECF No. 135-27, ¶11.**

This case has already been appealed to the Sixth Circuit that established the law of the case.[11] For the Fourth Amendment theories, the Sixth Circuit noted that the current Fourth Amendment claims in this case are "analytically distinct from… whether drawing the children's blood and screening it for diseases violated the children's Fourth Amendment right." *Kanuszewski*, 927 F.3d at 424. It held "if [it] is indeed Defendants' purpose in retaining the children's blood samples [to conduct research on children's stored blood samples and seek to derive profit from the children's samples by selling them to third parties], then their ongoing, indefinite seizure of the samples is unreasonable." *Id.* at 425. An unreasonable search-and-seizure is unconstitutional under the Fourth Amendment.

For the substantive due process theories, the Sixth Circuit held that—

> Plaintiffs allege that after screening children's blood samples for diseases, Defendants retain the samples, transfer the samples

[11] "Upon remand of a case for further proceedings after a decision by the appellate court, the trial court must proceed in accordance with the mandate and the law of the case as established on appeal… implement[ing] both the letter and the spirit of the mandate, taking into account the appellate court's opinion and the circumstances it embraces." *United States v. Moored*, 38 F.3d 1419, 1421 (6th Cir. 1994).

> to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties. Plaintiffs allege that these actions are undertaken without informed parental consent. [Assuming these [above] allegations are true], Defendants' actions constitute a denial of the parents' fundamental right to direct the medical care of their children, and their actions must survive strict scrutiny.

*Id.* at 420. Therefore, if Plaintiffs prove the above underlined passage, the Sixth Circuit held that it "constitute[s] a denial of the parents' fundamental right" and thus must survive further "strict scrutiny" review. *Id*.

Undoubtedly, that is a near impossible standard for the State Defendants going forward so they only loosely address the required analysis and standards. It is an automatic presumption that the State Defendants' actions are unconstitutional. *Lac Vieux Desert Band of Lake Superior Chippewa Indians v. Mich. Gaming Control Bd.*, 276 F.3d 876, 879 (6th Cir. 2002) ("[w]e start by presuming that the [regulation] is unconstitutional"). They, not the Plaintiffs, have the shifted burden, *Middleton v. City of Flint*, 92 F.3d 396, 404 (6th Cir. 1996), of proving a compelling government interest with narrow tailoring, *Ondo v. City of Cleveland*, 795 F.3d 597, 608 (6th Cir. 2015). The means chosen to accomplish the government's asserted purpose must be "specifically and narrowly framed to accomplish that purpose." *Grutter v. Bollinger*, 539 U.S. 306, 333 (2003). The government must also present actual ***evidence*** of the "ineffectiveness of proposed alternatives."

*Johnson v. City of Cincinnati*, 310 F.3d 484, 504 (6th Cir. 2002). Administrative convenience for the government is not a compelling justification when advanced against a fundamental right. *Frontiero v. Richardson*, 411 U.S. 677, 690 (1973).

With all these burdens, a regulation or law subject to strict scrutiny is "always or nearly always… struck down." *Mass. Bd. of Retirement v. Murgia*, 427 U.S. 307, 319 (1976) (Marshall, J., dissenting). As explained herein (and in the parallel motion for summary judgment, **ECF No. 135**), the State Defendants, as predicted in *Murgia*, did not meet their burden. By that failure, summary judgment cannot be granted in favor of Plaintiffs.

## STANDARD OF REVIEW

A motion for summary judgment should be granted if the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FRCP 56(a). The focus must be "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby*, 477 U.S. 242, 251-252 (1986). "The fact that the parties have filed cross-motions for summary judgment does not mean, of course, that summary judgment for one side or the other is necessarily appropriate." *Parks v. LaFace Records*, 329 F.3d

437, 444 (6th Cir. 2003). Instead, the Court must apply the well-recognized summary judgment standards when deciding such cross motions: when this Court considers cross motions for summary judgment, it "must evaluate each motion on its own merits and view all facts and inferences in the light most favorable to the nonmoving party." *Westfield Ins. Co. v. Tech Dry, Inc.*, 336 F.3d 503, 506 (6th Cir. 2003).

## COUNTER ARGUMENT

Looking to the law of the case established by the Sixth Circuit, the lack of required proofs by the State Defendants, and presented arguments being nothing more than platitudes, their summary judgment must be denied.

### I. Substantive due process has been violated.

In *Kanuszewski*, the Sixth Circuit held if the State Defendants "retain the samples, transfer the samples to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties… without informed parental consent,"[12] "Defendants' actions constitute a denial of the

[12] It is Plaintiffs long repeated assertion that *informed* consent was never obtained from parents. The "motivating force and purpose" of the doctrine of informed consent is aiding the individual "in making an important decision regarding medical care." *Carr v. Strode*, 79 Haw. 475, 485, 904 P.2d 489 (1995). It precludes any "conspiracy of silence." *Id.* The doctrine of informed consent requires disclosure of the alternatives to and risks of a particular course of action, so as to enable the person to intelligently decide whether or not to undergo the same. E.g. *Dessi v. United States*, 489 F. Supp. 722, 727 (E.D. Virg. 1980). Michigan embodies an excellent general understanding. See MCL 333.17020. Such consent was not obtained here. **ECF No. 135-25; ECF No. 135-26; ECF No. 135-27.**

parents' fundamental right to direct the medical care of their children, and their actions must survive strict scrutiny." *Kanuszewski*, 927 F.3d at 420. The State Defendants' motion does not dispute this is occurring. See **ECF No. 147, PageID.4201-4203.** Plaintiffs have easily established the same. **ECF No. 135, PageID.1905-1924**; see also **ECF No. 147-4, PageID.4249**; **Exhibit H** (confirming existence of infants' samples in Biobank and BioTrust warehouses). As such, the State Defendants' actions "constitute a denial of the parents' fundamental right to direct the medical care of their children" and such only survives if it passes strict scrutiny. *Kanuszewski*, 927 F.3d at 420. Such a designation means laws and regulations—

> affecting constitutional rights must be drawn with precision and must be tailored to serve their legitimate objectives. And if there are other, reasonable ways to achieve those goals with a lesser burden on constitutionally protected activity, a State may not choose the way of greater interference. If it acts at all, it must choose less drastic means.

*Dunn v. Blumstein*, 405 U.S. 330, 343 (1972) (cleaned up). The "heavy burden of justification is on the State" and requires post-screening activities as state action be "closely scrutinized in light of its asserted purposes." *Id.* Stated another way, the government action "will be upheld only when they are narrowly tailored to a compelling governmental interest." *Kanuszewski*, 927 F.3d at 419 (quoting *Seal v. Morgan*, 229 F.3d 567, 574-575 (6th Cir. 2000)).

A compelling interest is an interest "of the highest order." *Wisconsin v. Yoder*, 406 U.S. 205, 215 (1972). What do the State Defendants claim is the compelling interest? It is not really all that clear despite federal law requiring a level of "precision." *Dunn*, 405 U.S. at 343. The discussion is on PageID.4220-4122. It appears to be machine/testing calibration. In the vaguest follow-up, they also seeking to assert unspecified general population research as a compelling interest. The State Defendants cite no authority which teaches or even suggests that medical machine calibration or general population research is a "compelling" interest. Neither is a compelling interest in a constitutional sense—an interest of the highest order. [13]

But even if this Court were to somehow believe such was a compelling interest (which it is not), they also fail narrow tailoring. Keeping residual blood samples for the State Laboratory's machine calibration certainly does not require that Plaintiffs' spots be sold or transferred to the Biobank or third-party researchers. And the State Defendants fail to show that keeping *everyone's* blood samples since 1984 is necessary for basic machine calibration. See **ECF No. 135-13, PageID.2186** ("As part of the NBS process, *some* [not all] of the residual dried blood spots are used by the MDHHS

[13] For example, traffic safety is a "substantial" government interest but fails to be a *compelling* one. *Thomas v. Bright*, 937 F.3d 721, 733 (6th Cir. 2019).

Laboratory for NBS quality assurance, test improvement, and test development."). Moreover, even assuming that it is true that 5,000 samples are needed to calibrate a machine (which is telling that no machinery documentation of the same was provided by the State Defendants[14,15]), gallons of blood can be easily purchased from the marketplace from voluntary donors.[16]

And even if the State Defendants argues it needs to keep just the samples that previously screened "positive" for future research as a compelling interest, they fail to explain why they (non-narrowly) then keep *everyone's* (including the infants') spots—indefinitely—who screen negative—and then transfer them to the Biobank—and then sell them to third parties for use and never to be returned for use in machine calibration at the State Laboratory.

As for general population research, obtaining fully informed parental

[14] As noted about the BioTrust itself, most blood spots are never used—calling into serious and direct contradiction the argued need for millions of indefinitely stored blood spots. See **Exhibit G** (bates-stamp 001324).

[15] The production of no evidence when strong objective evidence should be available is telling. "Silence then becomes evidence of the most convincing character." *Interstate Circuit, Inc. v. U.S.*, 306 U.S. 208, 225-226 (1939).

[16] See, e.g., https://bioivt.com/biofluids-blood-derived ("Normal human blood products are collected from consented donors under IRB-approved protocols at facilities located in the United States and Europe, using BioIVT Standard Operating Procedures. This allows us to customize every order according to your exact specifications while maintaining the highest level of product quality.")

consent outside the aftermath of childbirth is a narrower tailored means to effectuate the government's interest in the same against parents' fundamental rights. A more narrowly tailored way to operate the post-screening population research component would be to secure the required informed parental consent in an actual non-coercive way at a time in the months or weeks leading up to (or after) the birth so as to give sufficient time and opportunity consult with medical and legal experts one-on-one, conduct research, investigate Defendants' assertions, and secure fully and complete answers whether to participate in the Newborn Screening Program, the Michigan BioTrust for Health, and the Michigan Neonatal Biobank. The State Defendants have each mother's full contact information and could obtain informed parental consent by direct communication (including with confirmed delivery of the brochure) via US mail or by phone call. See **Exhibit J** (full contact information collected at time of heel stick test).

In short, the State Defendants fail to have a compelling government interest, fail narrow tailoring and, under *Johnson*, fail to provide actual evidence of the ineffectiveness of more narrowly tailored alternatives.

## II. The Fourth Amendment has been violated.

In *Kanuszewski*, the Sixth Circuit observed "it does not seem that the health of the child justifies the state in taking any actions with respect to the

blood samples after it has finished screening the samples for diseases. *Kanuszewski*, 927 F.3d at 425. The panel was right. **ECF No. 135-42, PageID.2432.** The Sixth Circuit goes to observe that "Plaintiffs allege that Defendants conduct research on children's stored blood samples and seek to derive profit from the children's samples by selling them to third parties." *Kanuszewski*, 927 F.3d at 425. *If this is indeed Defendants' purpose in retaining the children's blood samples, then their ongoing, indefinite seizure of the samples is unreasonable. Id.*

Using this law of the case, Plaintiffs on remand have proven (and the State Defendants do not contest) that Defendants do, in fact, "conduct research on children's stored blood samples and seek to derive profit from the children's samples by selling them to third parties." See, e.g., **Exhibits C, D, and I**; see also **ECF No. 135.** The Fourth Amendment protects against unreasonable searches and seizures. U.S. Const. amend. IV. An unreasonable search-and-seizure violates the Fourth Amendment. "No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pac R Co v Botsford*, 141 U.S. 250, 251 (1891). As such, the State Defendants have failed to show entitlement

to summary judgment.

## III. Consent is either lacking or insufficient.

The primary thrust of the State Defendants' case-wide defense centers on consent. If a government obtains sufficient consent, what is unconstitutional action is excused and does not offend the Constitution. *Davis v. United States,* 328 U.S. 582, 593-594 (1946). However, constitutional rights are personal, *Broadrick v. Oklahoma*, 413 US 601, 610 (1973), and waiver of constitutional rights are never presumed or treated lightly. Consent must be obtained in a voluntary and free fashion. *Bumper v. North Carolina*, 391 U.S. 543, 548 (1968). Consent is only voluntary when it is "unequivocal, specific and intelligently given, uncontaminated by any duress or coercion." *United States v. McCaleb*, 552 F.2d 717, 721 (6th Cir.1977); *United States v. Worley*, 193 F.3d 380, 386 (6th Cir. 1999). The burden of proving that the consent obtained was voluntary is on the government, *Tarter v. Raybuck*, 742 F.2d 977, 980 (6th Cir. 1984), and such "must be proved by clear and positive testimony," *United States v. Scott*, 578 F.2d 1186, 1188-1189 (6th Cir.1978). Moreover, courts must all consider the circumstances surrounding the obtainment of consent for "more subtle forms of coercion that might flaw [an individual's] judgment." *Schneckloth v. Bustamonte*, 412 U.S. 218, 227 (1973). The Court starts from the

presumption against any waiver of constitutional rights. *Tarter,* 742 F.2d at 980.

The State Defendants self-conclude, without analysis, they have obtained sufficient consent from each infant's parent. Yet, contrary to the *Scott* standard, they offer no clear and positive testimony of the same. They also fail to offer any evidence of the circumstances surrounding the obtainment of consent from each parent or offer evidence that consent was "unequivocal, specific and intelligently given" by each parent without duress or coercion. Instead, they present what they call "consent cards" for only seven of the nine children-plaintiffs and nothing more (despite rifling through literally thousands of pages of highly-private medical records of each infant and their mothers over their objections, see **ECF No. 121**).

**A. There was no consent obtained for D.W.L. and M.T.L.**

For the two infants where no consent cards were produced (D.W.L. and M.T.L.), this was not by accident—no consent was *ever* sought or obtained. See **ECF No. 135-41, PageID.2412** ("we do not have active informed consent for children who were born before May 1st, 2010."). Before 2010, the State Defendants never sought consent of any type from parents. **ECF No. 147-12, PageID.4284-4285.** As such, the State Defendants lack any parental informed consent as to both the samples of D.W.L. and M.T.L.

and their data retained from the newborn screening process.[17] The State Defendants failed their burden mandated of them.

### B. There is insufficient consent for the seven infants born after 2010.

The matter goes slightly deeper for the seven infants born after 2010. Unlike the State Defendants, Plaintiffs have provided evidence of the circumstances surrounding the allege obtainment of the allege consent. **ECF No. 135-25; ECF No. 135-26; ECF No. 135-27.** First, each parent averred that no one from the birthing hospital or from the State (including its officials, agents, or partners or these Defendants) communicated with them regarding the risks (medical, legal, etc), the benefits, and any alternatives [as to] the Michigan BioTrust for Health regarding the post-testing retention, storage, or uses of the blood samples by third parties ("biobanking") like the Michigan Neonatal Biobank or their customers like third-party scientists and researchers. ***Id.*** Second, each parent averred that before the infants' births and thereafter, none were provided any information describing the post-testing biobanking program known as the Michigan BioTrust for Health or Michigan Neonatal Biobank and were never provided a copy of any

[17] The State Defendants claim that the MDHHS IRB (i.e. the State Defendants' colleagues) waived consent. But informed *parental* consent is required. *Kanuszewski*, 927 F.3d at 420 (it constitutes a denial of the parents' fundamental rights to "retain the samples, transfer the samples to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties… *without informed parental consent.*").

informational brochure about Newborn Screening Program. ***Id.*** They did "not know, realize, or understand that these Defendants had seized and indefinitely retained our children's blood samples or "blood spots" in a warehouse in Lansing with the Michigan BioTrust for Health or in a warehouse in Detroit with a private non-profit entity known as the Michigan Neonatal Biobank." ***Id.*** They also confirmed they also never "knew the Defendants (including its partners like the Biobank and Dr. Yancey) marketed and made our children's blood spots available for distribution, use, testing, and other uses, including by for-profit and academic researchers and scientists, who extract and use children's personal and deeply-private medical and genetic information/data for their own research projects—whether for-profit or otherwise." ***Id.*** This fails informed parental consent.

**1. The consent cards are insufficient proof.**

The State Defendants present various signed versions of their "consent cards." However, the circumstances of how each were obtained reveals a "subtle form of coercion" that flawed each parent's uninformed judgment. Each parent has no memory of signing these forms. None were provided a copy of the brochure. ***Id.***[18] The reason why there is no memory

[18] It was conceded that the lack of brochure means a lack of informed consent. **ECF No. 135-42, PageID.2433**.

of parents signing the documents is because seeking consent in the immediate hours following the arduous, body-damaging, stressful, tiring, and painful experience of child birth (which includes receiving and being under the influence powerful medications related to birthing) is the worst possible time to have a parent make a fully informed, reasoned decision. Asking for consent at such a time "appears to intentionally seek consent when full information is not and cannot be made available to mothers and fathers, and when the person being asked, normally the mother, is in no condition to make such a decision, i.e. in the postpartum recovery process in the hospital." **ECF No. 135-25; ECF No. 135-26; ECF No. 135-27.** We know parents are us tot sufficient informed under the current process. Elizabeth R. Eisenhauer, Ph.D., RN, *Mothers' Decisions About Donating Newborns' Blood Spots for Research: A Qualitative Study*, 33 J. PERINAT. NEONAT. NURS. 361 (2019) (**ECF No. 135-28**). The State Defendants offer no evidence why they are not using the far more reasonable time in the months or weeks leading up to (or alternatively in the weeks and months after) the birth of the children, when parents would have had the opportunity to consult with medical and legal experts one-on-one, conduct research, investigate Defendants' assertions, and secure fully and complete answers whether to participate in the Newborn Screening Program, the Michigan BioTrust for Health, and the Michigan

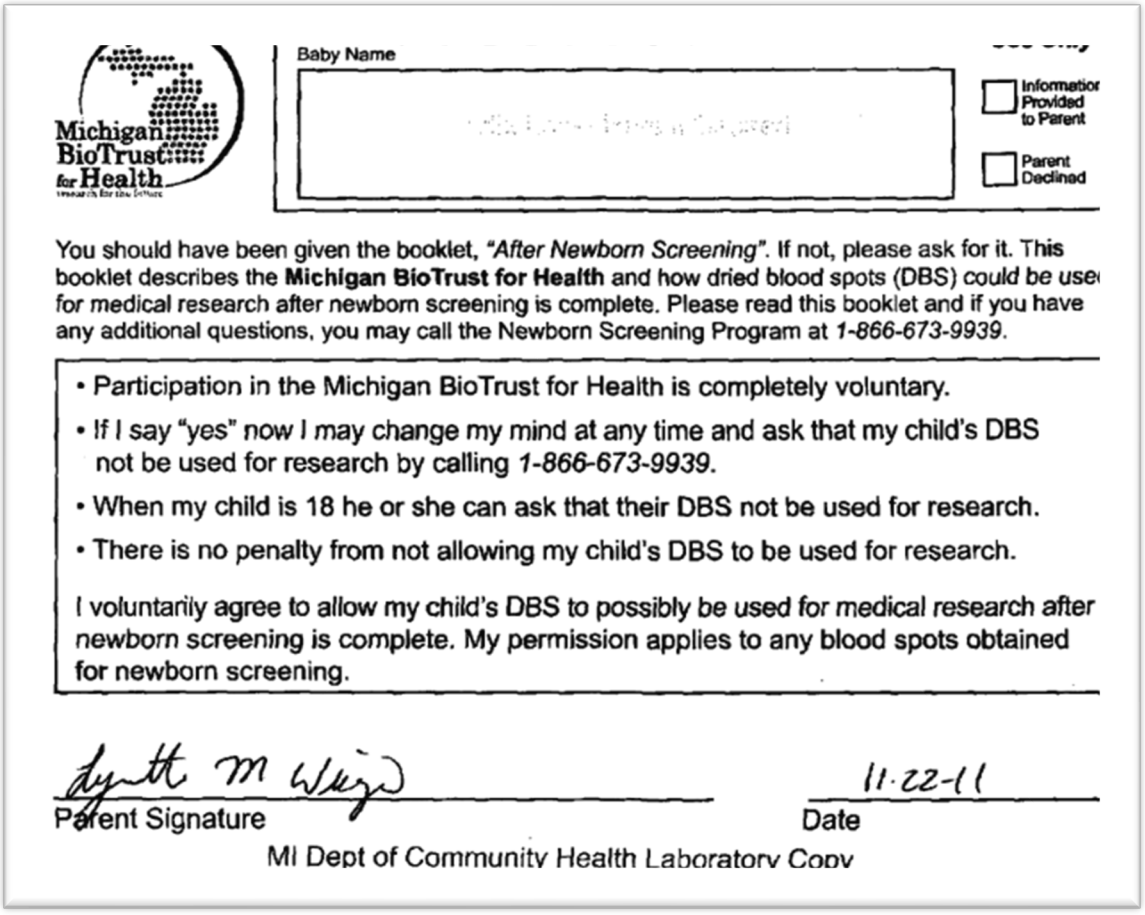
Neonatal Biobank.[19] **ECF No. 135-42, PageID.2434**. The real reason is because the State Defendants fear many parents will simply say "no" if the entire scope of the program—from extraction to sale of the infants' blood spots and deeply-private medical and genetic information/data—were revealed, i.e. there would be a greater number of parents, like these plaintiff-parents, who would simply decline participation.

In their brief, the State Defendants counter that the State Defendants have "not used any DBS contrary to the expressed wishes of the parents." This is both an incomplete statement and an untrue one. As these parents all confirm, had they "known the full and complete scope of the Newborn Screening Program, the Michigan BioTrust for Health, and Michigan Neonatal Biobank, [they] would have never provided any consent or authorization for any part of this program as it is both invasion and evisceration of our children's personal and medical privacy and personal autonomy, and improperly invades our rights as parents to make all decisions concerning the medical care of our children." **ECF No. 135-25;**

[19] Undoubtedly, the State Defendants could alternatively seek consent in weeks *after* the newborn screening tests when moms and dads have comfortably settled in back at home following the birth of their new child. While maybe a bit sleep deprived, parents would have a better opportunity to make an informed choice. The current contact information of every mother is fully secured by the State Defendants via the hospital as part of the NBS data-extraction process. **Exhibit J**; see also **ECF No. 135-18, PageID.2203** (requiring mom's mailing address).

**ECF No. 135-26; ECF No. 135-27.** As such, the current and ongoing retention of their infants' spots and the deeply-private medical and genetic information/data extracted from the newborn screening tests is contrary to the expressed wishes to parents—who were never sufficiently told of and explained the true scope and depth of the State Defendants' actions.

Looking to each card signed by mothers in immediate aftermath of arduous, body-damaging, stressful, tiring, and painful experience of child birth, the older versions of the card provide essentially no information whatsoever. Here is a sample from 2011—



Michigan BioTrust for Health

Baby Name

Information Provided to Parent

Parent Declined

You should have been given the booklet, *"After Newborn Screening"*. If not, please ask for it. This booklet describes the **Michigan BioTrust for Health** and how dried blood spots (DBS) could be used for medical research after newborn screening is complete. Please read this booklet and if you have any additional questions, you may call the Newborn Screening Program at *1-866-673-9939*.

- Participation in the Michigan BioTrust for Health is completely voluntary.
- If I say "yes" now I may change my mind at any time and ask that my child's DBS not be used for research by calling *1-866-673-9939*.
- When my child is 18 he or she can ask that their DBS not be used for research.
- There is no penalty from not allowing my child's DBS to be used for research.

I voluntarily agree to allow my child's DBS to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening.

Parent Signature

11-22-11

Date

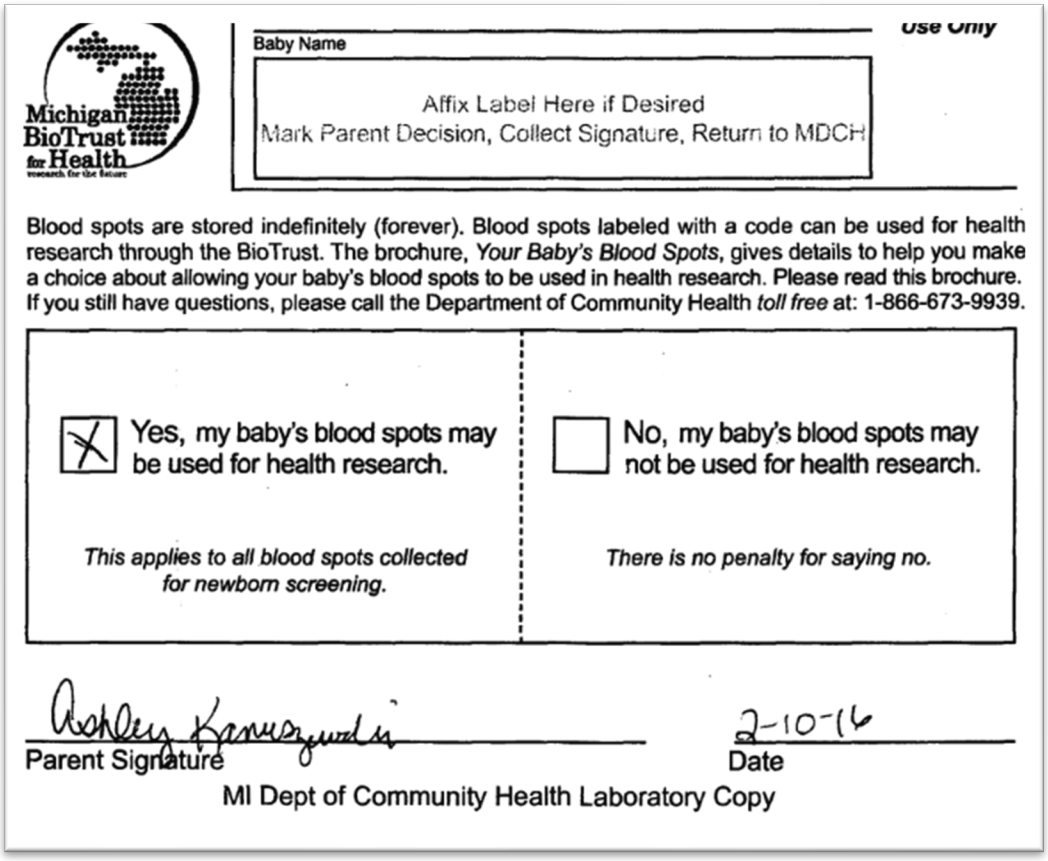
MI Dept of Community Health Laboratory Copy

When this form is presented to mothers in the hospital, no one communicated the risks, the benefits and any alternatives regarding the retention, storage, or uses of the blood samples by third parties like the Michigan Neonatal Biobank or third-party researchers and scientists over whom we have no control. No one presented the referenced "booklet."[20] By signing the form, this simply asks for the "possibility" of the samples of "medical research" by the State Defendants "after newborn screening is complete." There is no explanation that what the State Defendants really meant was indefinitely storage of the same after transferring the same to a non-profit corporation, the Biobank, who in turns sells them to outside researchers. There is no mention of the Biobank; no mention of the significant revenue stream of several million dollars; no mention of development of sellable products for academic and commercial researchers. There is also no consent sought or obtain to indefinitely or long-term retain the deeply-private medical and genetic information/data extracted from the

[20] The Court should note that there is a difference between the pamphlet the Legislature required under MCL 333.5431 and the booklet/pamphlet referenced here. Compare **ECF No. 147-3** with **ECF No. 147-10**. Moreover, the booklet submitted by the State Defendants is dated October 2017 (see third panel, **PageID.4278**) which is after the births of nearly every infant in this case. This booklet/pamphlet is essentially irrelevant because none were ever provided to these parents at the time of the birth of their respective infants. **ECF No. 135-25** (¶¶4-5); **ECF No. 135-26** (¶¶4-5); **ECF No. 135-27** (¶¶4-5).

newborn screening tests.[21] This requested consent—coupled with the timing it was sought—fails to secure "unequivocal, specific and intelligent" consent. Again, we can be sure that was not understood at the time because all the parents have confirmed that knowing what they know now, none would have consented. **ECF No. 135-25; ECF No. 135-26; ECF No. 135-27.**

In 2016, the form changes—



Michigan BioTrust for Health

Baby Name

Use Only

Affix Label Here if Desired
Mark Parent Decision, Collect Signature, Return to MDCH

Blood spots are stored indefinitely (forever). Blood spots labeled with a code can be used for health research through the BioTrust. The brochure, *Your Baby's Blood Spots*, gives details to help you make a choice about allowing your baby's blood spots to be used in health research. Please read this brochure. If you still have questions, please call the Department of Community Health *toll free* at: 1-866-673-9939.

☒ Yes, my baby's blood spots may be used for health research.

*This applies to all blood spots collected for newborn screening.*

☐ No, my baby's blood spots may not be used for health research.

*There is no penalty for saying no.*

Ashley Kanerzuski

Parent Signature

2-10-16

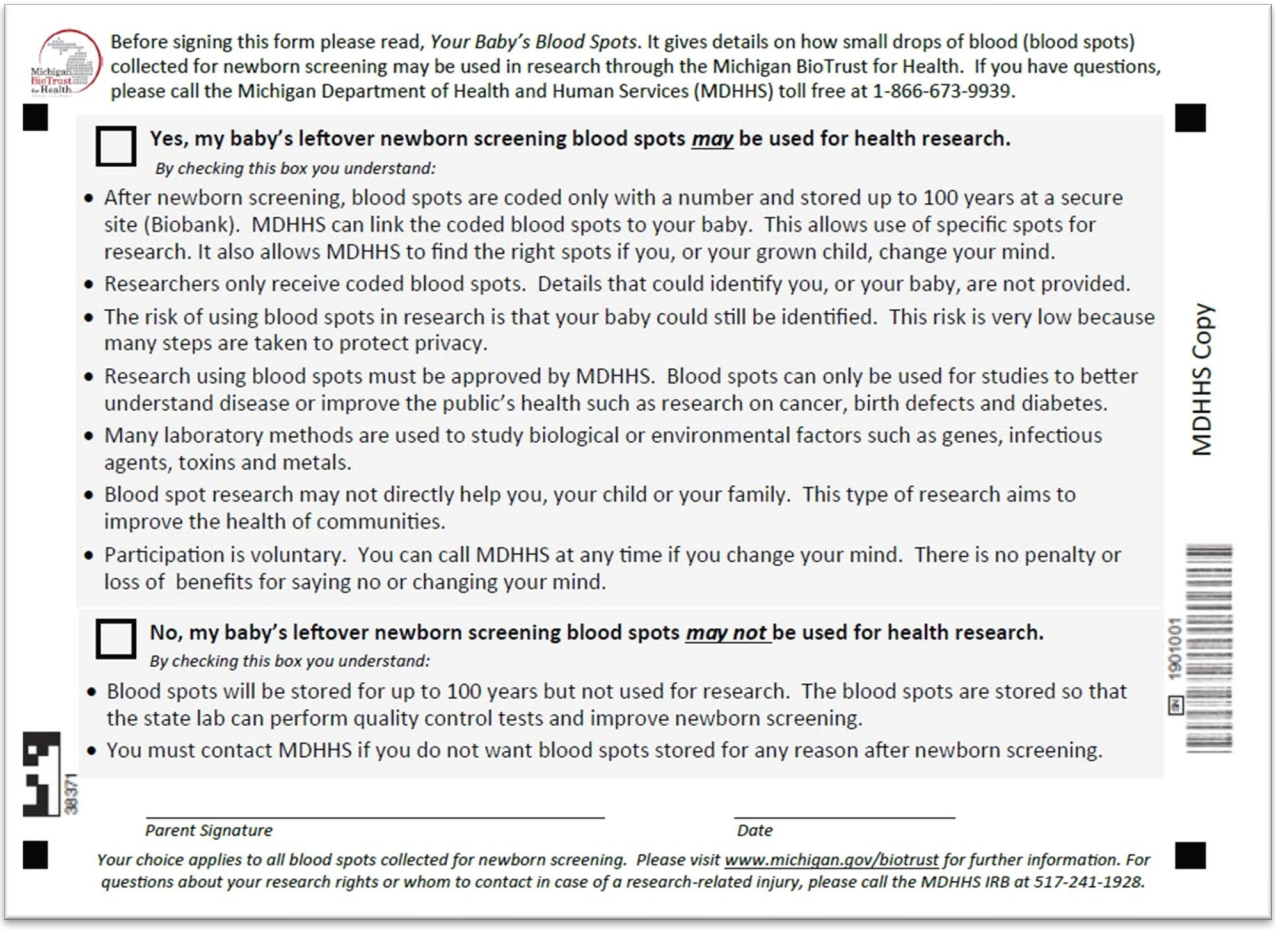
Date

MI Dept of Community Health Laboratory Copy

[21] One thing the State Defendants continue to neglect is that they are selling blood with linkage to deeply-private medical and genetic information/data from various health registries maintained by DHHS. See https://mnb.wayne.edu ("MDHHS can link blood spot specimens to Michigan's public health registries"); see https://mnb.wayne.edu/research/fees ("The dried blood spots [purchased from the Biobank] can be linked to information found in the State's public health registries.").

This time it is not for *medical* research but for "***health*** research." Why the change is unclear and unexplained. This version does not reference the "booklet" but instead a "brochure" now entitled "Your Baby's Blood Spots." It is true this form has ever-so slightly more information, including a statement (not a request to the parent) the State would be indefinitely (not 100 years) storing the blood spots and that "blood spots labeled with a code can be used for health research through the BioTrust." It does not explain what the BioTrust is or what it does. Like before, there is no mention of the Biobank or the outside researchers. There is no mention of the significant revenue stream of several million dollars and no mention of the development of sellable products for academic and for-profit commercial researchers. Also like before there is also no consent sought or obtain to indefinitely or long-term retain the deeply-private medical and genetic information/data extracted from the newborn screening tests.

Finally, in 2017, the form changes again.



Before signing this form please read, *Your Baby's Blood Spots*. It gives details on how small drops of blood (blood spots) collected for newborn screening may be used in research through the Michigan BioTrust for Health. If you have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

☐ **Yes, my baby's leftover newborn screening blood spots *may* be used for health research.**

*By checking this box you understand:*

- After newborn screening, blood spots are coded only with a number and stored up to 100 years at a secure site (Biobank). MDHHS can link the coded blood spots to your baby. This allows use of specific spots for research. It also allows MDHHS to find the right spots if you, or your grown child, change your mind.
- Researchers only receive coded blood spots. Details that could identify you, or your baby, are not provided.
- The risk of using blood spots in research is that your baby could still be identified. This risk is very low because many steps are taken to protect privacy.
- Research using blood spots must be approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health such as research on cancer, birth defects and diabetes.
- Many laboratory methods are used to study biological or environmental factors such as genes, infectious agents, toxins and metals.
- Blood spot research may not directly help you, your child or your family. This type of research aims to improve the health of communities.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

MDHHS Copy

☐ **No, my baby's leftover newborn screening blood spots *may not* be used for health research.**

*By checking this box you understand:*

- Blood spots will be stored for up to 100 years but not used for research. The blood spots are stored so that the state lab can perform quality control tests and improve newborn screening.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

1901001

38371

*Parent Signature* *Date*

*Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.*

This time the form undoubtedly has more details, but, characteristically, still is vague, misleading, and in some instances contain untrue statements. For example, the first bullet says that blood samples are stored for "up to 100 years." That is untrue—we know it is actually indefinitely. **Exhibit F** (bates-stamp 0044). There is no reference to the samples being used by law enforcement or for crime victim identification. It also speaks of research "through the Michigan BioTrust for Health"—an entity that conducts no research itself. There is one vague reference to the "(Biobank)" while no

mention of the significant revenue stream of several millions of dollars; and no mention of the development of sellable products from the excess samples for academic and commercial researchers outside of uses by the State laboratory. There is no disclosure of available data linkages to health data. **Exhibit K.** Interestingly, there is not an option to simply just never retain samples after newborn screening testing is complete. Why not has never been explained.

These forms are designed on a false choice. There are always only two choices. There is no available option for a parent to decline altogether as to ***any*** post-screening retention, storage, transfer, or uses. And even if the parent does go and destroy the samples immediately thereafter, the State still keeps and uses the infants' personal and deeply-private medical and genetic information/data extracted during the tests without parental consent.

**C. The State Defendants are oddly quiet.**

For its motion for summary judgment, the State Defendants never parse the differences between these separate versions of their forms to show that the informed parental consent was obtained and that obtainment was "unequivocal, specific and intelligent given, uncontaminated by any duress or coercion," as is their burden. The government's use of uninformed consent, tainted by the coercion of "the [faux] ask" occurring during the

immediate aftermath of child birth, is "too weak" to remove or cure the taint of unconstitutional action, especially when uninformed consent the intended product of such unconstitutional action. *US v. Castillo*, 864 F. Supp. 1090, 1099 (D. Utah 1994). Further, the State Defendants do not explain why they seek to obtain consent when moms and dads are clearly not at their best to make informed, rational decisions, but instead in the aftermath and fog-of-war of childbirth. The reason is not a secret—it is to reduce or eliminate a parent asking questions and then saying no. Such tactics show how guileful and incomplete this consent process actually is. Again, the use of platitudes rather than meeting the legal obligations imposed for constitutional review does not save a government-desired program even if started and tried to be operated with noble intent.

**IV. The self-made administrative process offers no cure.**

Like the Biobank, the State Defendants also rely heavily on the self-made administrative process to request the destruction of samples after the fact. The process is not mandated by statute (see MCL 333.5431)—it is operated at the good-graces of the State Defendants which they need not follow if they so choose. Notwithstanding, this argument is precluded by *Kanuszewski*. Even more problematic, this non-judicial remedy is an incomplete one.

Like Dr. Yancey, the State Defendants argue that because the parents can use a made-up, non-statutory state administrative process to cause the destruction of the samples that this civil rights case again them is precluded. See **ECF No. 147, PageID.4220.** The Sixth Circuit already rejected that argument. *Kanuszewski*, 927 F.3d at 409 fn.5. The Supreme "Court has stated categorically that exhaustion is not a prerequisite to an action under § 1983, and we have not deviated from that position in the 19 years" since first being decided. *Patsy v. Fla. Bd. of Regents*, 457 U.S. 496, 507 (1982). Why they keep pounding the argument is baffling.

But let's assume the parents were to make the request today. They have no basis to know that the samples were, in fact, destroyed because Michigan law does not require the State Defendants to fulfill a parent directive. For example, the undersigned made this type of request and heard nothing back from DHHS, and had to eventually sue in the Michigan Court of Claims to get answers. Then a letter dated November 14, 2017 was produced in initial discovery (which was never received in November 2017) asserting that only two (for which we know there are at least four or five[22])

[22] The State Defendants confirm that "the other ***five***" spots leftover "are likewise de-identified, assigned the same anonymous numeric code, and stored" at the Biobank. **ECF No. 147, PageID.4202**; see also **Exhibit G** (bates-stamp p001322). What happened to the other three or four bloods spots from young Mr. Ellison?

blood spots "*were* destroyed" on November 28, 2017—supposedly some two weeks ***after*** the letter was purportedly dated. **Exhibit E.** How can something be previously (i.e. "were") destroyed some two weeks into the future? Clearly, a fabricated exhibit or at least one which creates grave doubts.

Moreover, Dr. Lyon-Callo testified at deposition that samples can be "returned" if a request is made by parents. **ECF No. 135-41, PageID.2424.** Yet, by their briefing and submitted evidence, Defendants offer no means—administrative or otherwise—to effectuate a return-to-parents or supplied any proof that such occurs. It is because it does not. See **ECF No. 147-5; ECF No. 147-6**; **ECF No. 147-7**. Just as easy as Dr. Lyon-Callo "made up" that the return of spots is available to parents, she (as the one in charge) can simply decline the demanded directives of parents from these non-statutory, policy-based processes. From these experiences, the parents, represented by the undersigned, know that the "administrative" process is rife with uncertainty, suffers from as politically needed document fabrications, is tainted by possible fraud, and results in only partial destruction leaving two or three unaccounted-for blood spots. Moreover, the administrative process does not provide any means to destroy or regain singular control over the children's personal and deeply-private medical and genetic information/data extracted during the screenings being retained in government files and

databases.

To say, as the State Defendants claim, that this case should be precluded because they *might*—though rife with uncertainty—provide a partial and incomplete outcome makes no sense. And more critically, the Supreme Court has "categorically" confirmed that exhaustion is not a prerequisite to an action under § 1983. The argument fails.

## V. The State Defendants are the correct parties.

In an odd argument, the State Defendants assert that they, sued in their official capacities, are the incorrect parties to name because the medical professionals (who took the blood sample under threat of criminal charges, **ECF No. 135-21, PageID.2220**) should have been the ones to obtain the correct form of consent. **ECF No. 147, PageID.4230-4232.** The argument misses the mark. Once the newborn screenings are complete, the State Defendants want to keep children's personal and deeply-private medical and genetic information/data extracted during the tests and the "residual" blood spots. In order to assert that permission has been given for the State Defendants to do so, it must prove the obtainment of sufficient consent. Yes, the State Defendants can rely upon the consent obtained by agents (even if conscripted) on their behalf. However, if those agents fail to actually obtain informed consent, the State Defendants, in turn, have not claim to have

sufficient consent to support the latter's uses which thusly remain unauthorized. As such, the State Defendants are the right parties. **ECF No. 135-41, PageID.2409**.[23]

## VI. Declaratory and injunctive relief is warranted.

### A. Plaintiffs are entitled to injunctive relief.

The State Defendants next argue that even if they are violating the federal Constitution, an injunction should not be issued citing the standard for a preliminary injunction. The State Defendants are using the wrong test citing to *Barry v. Lyon*, 834 F.3d 706, 720-721 (6th Cir. 2016).[24] A constitutionally-wronged party is entitled to a permanent injunction when establishing that he or she suffered a constitutional violation and will suffer continuing irreparable injury for which there is no adequate remedy at law.



[23] Q I'd like to know who at the Michigan Department of Health and Human Services is responsible for overseeing or otherwise controlling the blood spots at the Neonatal Biobank?

A *** I think probably the simplest way to answer the question is that Dr. Shah and myself are responsible for the dried blood spots in the Michigan BioTrust program that are at the Michigan Neonatal Biobank for storage and distribution at the direction of the Michigan Department of Health and Human Services.

Q *** So I guess the reason why I'm asking would be is that if a -- say in this case a judge was to issue an injunction against both of you in your official capacities, you would have the ability to direct the blood spots to no longer go to the Biobank if that's what the judge so ordered; would that be correct?

A That is my understanding.

[24] In *Barry*, it was the State who argued that the "district court erred by granting a permanent injunction without addressing the well-established four-factor test that requires a plaintiff seeking injunctive relief to establish. The Sixth Circuit never made this their holding. The correct test comes from *Women's Medical* and *Kallstrom.*

*Women's Medical Professional Corp. v. Baird*, 438 F.3d 595, 602 (6th Cir. 2006) (citing *Kallstrom v. City of Columbus*, 136 F.3d 1055, 1067 (6th Cir. 1998)).

However, the State Defendants have highlighted an interesting question—has the Sixth Circuit's permanent injunction test in *Women's Medical* and *Kallstrom* been overruled by *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006)? Post-*eBay*, the Sixth Circuit still followed the traditional Sixth Circuit test. *EMW Women's Surgical Center PSC v. Friedlander*, 960 F.3d 785, 793 (2020) (*EMW I*); see also *Am. Civil Liberties Union of Kentucky v. McCreary Cty., Ky.*, 607 F.3d 439, 445 (6th Cir. 2010) (same after *eBay*). But then in another-similarly captioned but different case six months later explained—

> To obtain a permanent injunction, the plaintiffs must establish [to] have suffered a constitutional violation and will suffer continuing irreparable injury for which there is no adequate remedy at law. *Women's Med. Pro. Corp. v. Baird*, 438 F.3d 595, 602 (6th Cir. 2006) (quoting *Kallstrom v. City of Columbus*, 136 F.3d 1055, 1067 (6th Cir. 1998)).
>
> ***
>
> If they succeed in demonstrating an actual constitutional violation and continuing irreparable injury, the plaintiffs must also show "that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

*EMW Women's Surgical Center PSC v. Friedlander*, 978 F. 3d 418, 429 (2020) (*EMW II*) (cleaned up). If we follow *EMW I* or *EMW II*, the State Defendants still stated the wrong test. The question is whether the "public

interest" prong must now be satisfied post-*EMW II*?

Even with that extra requirement, an injunction is easily warranted.[25] Constitutional violations have been established. **ECF No. 135.** There is no other adequate remedy at law as damages have been precluded by standing and immunities doctrines by *Kanuszewski.* "When constitutional rights are threatened or impaired, irreparable injury is presumed." *Obama for America v. Husted*, 697 F.3d 423, 436 (6th Cir. 2012). The State Defendants continue to approve distribution of blood spots. See **Exhibit D** (receiving requests for and authorizing samples following filing of this suit). By retaining the samples without sufficient informed consent for use, Plaintiffs suffer continuing irreparable injury in form of constitutional injury via the interference with the infants' personal autonomy and the invasion and evisceration of their personal and medical privacy via the unauthorized retention of their blood samples containing extractable or deeply private medical and genetic information without sufficient informed parental consent, together with the State Defendants' ongoing retention of already extracted deeply private medical and genetic information in their files and databases. It is always in

[25] To be clear, injunctive relief is not the only remedy sought. Plaintiffs has minimally sought two forms of declaratory relief (**ECF No. 26, ¶118(a), (e)**), and four forms of injunctive relief, (**ECF No. 26, ¶118(f), (g), (h), (i)**). Moreover, the concurrently filed motion for summary judgment reserves the remedy portion to further briefing.

the public's interest to prevent violations of an individual's fundamental and constitutional rights, which. *Dodds v. United States Dep't of Educ.*, 845 F.3d 217, 222 (6th Cir. 2016). An injunction is a proper remedy.

**B. Plaintiffs are entitled to declaratory relief.**

Lastly, the State Defendants argue that declaratory relief should not issue. Their reasoning is difficult to parse because it is essentially a version of we-simply-don't-want-to-lose. Today, the State Defendants have ongoing control over these infants' blood spots after having transferred the same to another entity without sufficient informed parental consent and they still have the infants already extracted deeply private medical and genetic information in their files and databases without any consent from parents. The State Defendants have wronged Plaintiffs and a final federal declaratory judgment would, at minimum, remedy some of those violations whose harm and injury are still ongoing. See Exhibit H (The State Defendants have failed to identify a valid *Grand Trunk* factor which aids their argument. The whole point of a federal judgment *is* to interfere with the actions of state official acting under state law. A federal court issues prospective injunctive and declaratory relief to compel a state official to comply with federal law. *S & M Brands, Inc. v. Cooper*, 527 F.3d 500, 507-508 (6th Cir. 2008). It prevents the state official from continuing to defer to state law and local policies when such results in

runs up against constitutional prohibitions. As such, this Court can and should declare that the conduct of the State Defendants acting under the color of law as being unconstitutional in violation of the Fourth and/or Fourteenth Amendments to the United States Constitution; and that their assertion of having obtained consent is false and has been exceeded and thereby rendering their actions unconstitutional. **ECF No. 26, ¶118(a), (e).**

**RELIEF REQUESTED**

Based upon the foregoing, the Court is requested to deny summary judgment in favor of the State Defendants and instead grant summary judgment against them in favor of Plaintiffs.

Date: May 7, 2021

RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison
OUTSIDE LEGAL COUNSEL PLC
PHILIP L. ELLISON (P74117)

Attorney for Plaintiffs

## CERTIFICATE OF SERVICE

I, the undersigned attorney of record, hereby certify that on the date stated below, I electronically filed the foregoing with the Clerk of the Court using the ECF system which will send notification of such filing to all counsel or parties of record.

Date: May 7, 2021

RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison
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